Citation:

Inoue K, Shono T, Toyokawa S, Kawakami M. Body mass index as a predictor of mortality in community-dwelling seniors. *Aging Clin Exp Res.* 2006 Jun;18(3):205-10.

PubMed ID: <u>16804366</u>

Study Design:

Prospective Cohort Study

Class:

B - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To assess the relationship between body mass index (BMI) and mortality rate in a sample population of Japanese seniors, 65 years old and older, residing at home.

Inclusion Criteria:

- 65 years of age or older
- Residing in Towa, Japan as of 1995
- Voluntarily participated in annual health check program for non-institutionalized residents

Exclusion Criteria:

None specified.

Description of Study Protocol:

Recruitment

• Sample included elderly residents who voluntarily participated in an annual health check program for non-institutionalized residents

Design: Prospective cohort study

Blinding used (if applicable): researchers were blind to subject identification

Intervention (if applicable): not applicable

Statistical Analysis

• Unpaired t-test and chi-square test: to explore associations between subject mortality and each collected variable

• in categorical analyses, BMI categories were:

• low: $< 18.5 \text{ kg/m}^2$

• normal: $18.5 - 25.0 \text{ kg/m}^2$

• high: $> 25.0 \text{ kg/m}^2$

- Univariate Cox proportional hazard models: to analyze the association between mortality and collected variables
- Multivariate Cox proportional hazard models: to analyze the association between mortality and BMI, after adjusting for other potential risk factors
 - baseline variables associated with mortality (P<0.10) during univariate analysis or pre-established risk factors for mortality were included in multivariate analysis
- Kaplan-Meier method used to examine the impact of survival curves for each of the three BMI levels on mortality
 - Wilcoxon log-rank test used to assess differences between curves

Data Collection Summary:

Timing of Measurements: baseline data collected in 1995; continuous update of mortality register for deaths; follow-up for 5 years.

Dependent Variables

Mortality

Independent Variables

• Body mass index (kg/m²): calculated from height and weight measured using standardized height and weight scales

Control Variables

- Sociodemographic characteristics: sex, age, living arrangements, impairment of activities of daily living (ADL)(items on transfer, eating, toileting, bathing and dressing), alcohol consumption (yes/no), and smoking (yes/no)
- Comorbidity: history on medically-treated hypertension, cerebrovascular disease, hyperlipidemia, diabetes, osteoarthritis/neuralgia, and other diseases
- Blood tests: serum lipids, creatinine and hemoglobin levels
- Blood pressure (BP): sitting BP measured after 5 minute rest; first and fifth phases of Korotkoff sounds were recorded as systolic (SBP) and diastolic (DBP)

Description of Actual Data Sample:

Initial N: N=1020 elderly residents

Attrition (final N): N=371 (36.4%) that voluntarily participated in health check program

Age: 65 years or older

Age distribution (%) (P<0.001)

Alive	Deceased
(N=334)	(N=37)

65-69	39.5	10.8
70-74	32.6	21.6
75-79	16.8	24.3
80-84	8.4	16.2
85+	2.7	27.0

Ethnicity: Japanese

Other relevant demographics: none specified

Anthropometrics

Body mass index:

• low (<18.5 kg/m²): N=54 (14.6%)

• normal (18.5-25.0 kg/m²): N=280 (75.5%)

• high (>25.0 kg/m²): N=37 (10.0%) (N=2 with BMI \geq 30)

Mean BMI

• Subjects alive (N=334): 21.5±3.0

• Deceased (N=37): 20.1±2.1

Location: Towa, Japan

Summary of Results:

Key Findings

- During 5 years of follow-up, deaths occurred in 10% (N=37) of the sample.
- In univariate Cox proportional hazard analysis, significant associations with mortality were found for male sex (HR=2.44, 95%CI: 1.26-4.70, P<0.01), age (HR=2.09, 95%CI: 1.64-2.67, P<0.001), and BMI (HR=0.82, 95%CI: 0.72-0.93, P<0.001).
- Survival curves indicated an increased chance of survival in the high BMI group and an increased risk of mortality in the low BMI group (P=0.005 by log-rank test).
 - Mortality curves of the low and middle subgroups appeared similar during the first two years of the study period.
- In multiple Cox proportional hazard analysis, significant independent associations with mortality were found for age (HR=2.07, 95% CI: 1.57-2.72, P<0.001), and BMI (HR=0.85, 95%CI: 0.74-0.98, P<0.05).

Other Findings

- In univariate analysis, male sex, age, BMI and serum creatinine were significantly associated with mortality.
- The mortality rate in the low BMI group was twice that in the normal BMI group
- No deaths were observed in the higher group.

Author Conclusion:

A low BMI appears to be an independent predictor of shortened survival, whereas a high BMI up to around 30.0 kg/m² does not. BMI may be a useful predictor of mortality among seniors living in the general non-institutionalized population.

Reviewer Comments:

- Low percentage of elderly residents who were potentially eligible for inclusion participated in the health check.
- Unclear of follow-up period of 5 years was long enough
- *Limitations as noted by authors:*
 - single measurement of BMI at baseline did not account for possible fluctuations over time that may influence outcomes
 - Only 2 subjects with BMI > 30; none with BMI of 32 or more
 - information not obtained about cause of death
- Strengths as noted by authors:
 - height and weight were measured
 - non-institutionalized population studied
 - no bias due to racial diversity

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the	N/A
	patients/clients/population group? (Not Applicable for some epidemiological studies)	

- 2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?
- 3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?
- 4. Is the intervention or procedure feasible? (NA for some epidemiological studies)

Validity Questions

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1.	Was the research question clearly stated?		Yes	
	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes	
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes	
	1.3.	Were the target population and setting specified?	Yes	

2.	Was the seld	ection of study subjects/patients free from bias?	Yes
	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
	2.2.	Were criteria applied equally to all study groups?	Yes
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
	2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	Were study	groups comparable?	Yes
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method	d of handling withdrawals described?	Yes
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	N/A
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindin	ng used to prevent introduction of bias?	Yes

	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		vention/therapeutic regimens/exposure factor or procedure and rison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A
	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
	6.6.	Were extra or unplanned treatments described?	N/A
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outco	mes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the stat	istical analysis appropriate for the study design and type of licators?	Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due t	o study's funding or sponsorship unlikely?	Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes

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